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## IAP6 Rec'd PCT/PTO 2 7 APR 2007

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Approved for use through 3/31/2007. OMB 0651-0021
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TRANSMETAL LESTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)

CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

NTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE US2004/041308

INTERNATIONAL FILING DATE 12/10/2004

INTERNATIONAL FILING DATE December 11, 2003

INTERNATIONAL APPLICATION NO. US2004/041308 TITLE OF INVENTION METHODS AND COMPOSITIONS FOR THE TREATMENT OF PROLACTIN-RECEPTOR RELATED DISORDERS APPLICANT(S) FOR DO/EO/US Ross G. CLARK Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: 1. 🔲 This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. 2. 🛛 This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. з. 🗔 This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. 🔲 The US has been elected (Article 31). 5. 🔲 A copy of the International Application as filed (35 U.S.C. 371(c)(2)) a.  $\bigsqcup$  is attached hereto (required only if not communicated by the International Bureau). has been communicated by the International Bureau. c. Li is not required, as the application was filed in the United States Receiving Office(RO/US) 6. 🔲 An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). a. is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). 7. Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. d. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 8. 🗌 9. 🖂 An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. 🔲 An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: 11. 🔲 An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. 🔲 An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. 🔯 A preliminary amendment. 14. 🔲 An Application Data Sheet under 37 CFR 1.76. 15. 🔲 A substitute specification. 16. 🔲 A power of attorney and/or change of address letter. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825. 17. 🖂 18. 🔲 A second copy of the published International Application under 35 U.S.C. 154(d)(4). A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 19. 🔲

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO-1390 (Rev. 09-2006)
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| U.S. APPLICATION NO. (If known, see 37 CFR 1.5)  10/582,047  |  |                                 | US2004/041308   |         | TRCA-004          |                        |              |  |
|--|--|---------------------------------|---|---------|-------------------|------------------------|--------------|--|
| 20. Other items or information: PTO Form 2038; Paper Copy of Sequence Listing; Copy of Missing Requirements; Return Postcard   |  |                                 |   |         |                   |                        |              |  |
| The followin   | ng fees have been sul  | nmitted                         |   |         |                   | CALCULATIONS           | PTO USE ONLY |  |
|  |  |                                 |   |         | \$300             | \$ 0.00                |              |  |
| 22. Examination  | n fee (37 CFR 1.492(   | c))                             |   |         | Ü                 | \$ 0.00                |              |  |
| If the written opinion p<br>IPEA/US inc<br>All other situations  | dicates all claims sati  |                                 |   |         |                   |                        |              |  |
| 23. Search fee If the written opinion p IPEA/US in Search fee (37 CFR 1. International Search R  | (37 CFR 1.492(b)) prepared by ISA/US of dicates all claims sating 445(a)(2)) has been all Searching Authority eport prepared by an ted to the US by the legared by the lega | \$ 0.00                         |   |         |                   |                        |              |  |
|  | TOTAL OF   | \$ 0.00                         |   |         |                   |                        |              |  |
| listing in compliar<br>(37 CFR 1.492(j)  | or specification and c<br>nce with 37 CFR 1.82<br>).<br>or each additional 50  |                                 | :   |         |                   |                        |              |  |
| Total Sheets   | Extra sheets   |                                 | each additional 50 or fract<br>ound up to a whole numbe |         | RATE              |                        |              |  |
| - 100 =  | - 100 = /50 = X \$250  |                                 |   | X \$250 | \$ 0.00           |                        |              |  |
| Surcharge of \$130.00 the date of commence   | for furnishing any of ment of the national s   | the search fee<br>stage (37 CFR | , examination fee, or the or 1.492(h)).                 | ath or  | declaration after | \$ 130.00              |              |  |
| CLAIMS   | <u> </u>   |                                 | NUMBER EXTRA  | RATE    |                   | \$                     |              |  |
| Total Claims   | ms <b>52</b> - 20 =  |                                 | 32  | × \$50  |                   | \$ 1600.00             |              |  |
| Independent Claims   | Independent Claims 4 - 3 =   |                                 | 1   |         | x \$200           | \$ 200.00              |              |  |
| MULTIPLE DEPENDI   | ENT CLAIM(S) (if app   | olicable)                       |   |         | + \$360           | \$ 360.00              |              |  |
|  |  | \$ 2290.00                      |   |         |                   |                        |              |  |
| Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.  |  |                                 |   |         |                   |                        |              |  |
| SUBTOTAL =   |  |                                 |   |         |                   | \$ 1145.00             |              |  |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).                        |  |                                 |   |         | \$ 0.00           |                        |              |  |
| TOTAL NATIONAL FEE =   |  |                                 |   |         | \$ 0.00           |                        |              |  |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property + |  |                                 |   | \$      |                   |                        |              |  |
| TOTAL FEES ENCLOSED =  |  |                                 |   |         | \$ 1145.00        |                        |              |  |
|  |  |                                 |   |         |                   | Amount to be refunded: | \$           |  |
|  |  |                                 |   |         |                   | Amount to be charged:  | \$1145.00    |  |
| 05/03/2007 GFREY1 00080019 10582047  |  |                                 |   |         |                   |                        |              |  |

| 01 FC:2615  | 800.00 OP |
|-------------|-----------|
| 02 FC:2616  | 180.00 OP |
| 03 FC:2617  | 65.00 OP  |
| 04 FC:2'614 | 188.88 RP |

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|  | •           |  |  |  |
|--|-------------|--|--|--|
| a.   |             | A check in the amount of \$ to cover the above fees is enclosed.   |  |  |
| b.   |             | Please charge my Deposit Account No. <u>50-0815</u> in the amount of <u>\$</u> to cover the above fees.  A duplicate copy of this sheet is enclosed.   |  |  |
| C.   | $\boxtimes$ | The Commissioner is hereby authorized to charge any additional fees (other than excess claim fees unless indicated above) which may be required, or credit any overpayment to Deposit Account No. <u>50-0815</u> . A duplicate copy of this sheet is enclosed. |  |  |
| d.   | $\boxtimes$ | Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.                                      |  |  |
| NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status. |             |  |  |  |
| SE   | END AL      | CORRESPONDENCE TO:   |  |  |
| Bozicevic, Field & Francis, LLP  |             |  |  |  |
|  |             | iversity Avenue, Suite  Paula A. Borden  NAME  |  |  |
| E  | ast Pa      | lo Alto  |  |  |
| C  | alifor      |  |  |  |
| 94   | 4303        | REGISTRATION NUMBER  |  |  |

FORM PTO-1390 (REV. 07-2005)



#### United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Viginia 22313-1450 www.uspto.gov

ATTY. DOCKET NO. FIRST NAMED APPLICANT U.S. APPLICATION NUMBER NO. TRCA-004 Ross G. Clark 10/582,047

INTERNATIONAL APPLICATION NO. PCT/US04/41308

I.A. FILING DATE

PRIORITY DATE

12/10/2004

12/11/2003

24353 BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303



**CONFIRMATION NO. 9278** 371 FORMALITIES LETTER \*OC000000023202186\*

Date Mailed: 04/02/2007

#### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Indication of Small Entity Status
- Copy of the International Application filed on 06/07/2006
- Copy of the International Search Report filed on 06/07/2006
- Copy of IPE Report filed on 06/07/2006
- Biochemical Sequence Listing filed on 06/07/2006
- U.S. Basic National Fees filed on 06/07/2006
- Priority Documents filed on 06/07/2006
- Specification filed on 06/07/2006
- Claims filed on 06/07/2006
- Abstracts filed on 06/07/2006
- Drawings filed on 06/07/2006
- Paper nucleotide sequence listings filed on 06/07/2006

The applicant needs to satisfy supplemental fees problems indicated below.

The following items MUST be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Additional claim fees of \$1080 as a small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.



• To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

#### SUMMARY OF FEES DUE:

Total additional fees required for this application is \$1145 for a Small Entity:

- \$65 Surcharge.
  - A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.
- Total additional claim fee(s) for this application is \$ 1080
  - \$900 for 36 total claims over 20.
  - \$180 for multiple dependent claim surchare.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web. <a href="https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html">https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html</a>

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

### PAULETTE R KIDWELL

Telephone: (703) 308-9140 EXT 216

### PART 1 - ATTORNEY/APPLICANT COPY

| U.S. APPLICATION NUMBER NO. | INTERNATIONAL APPLICATION NO. | ATTY. DOCKET NO. |  |
|-----------------------------|-------------------------------|------------------|--|
| 10/582,047                  | PCT/US04/41308                | TRCA-004         |  |

FORM PCT/DO/EO/905 (371 Formalities Notice)